SCALING-UP VACCINE MANUFACTURING IN AFRICA

The Why, How, and What's Next for this Agenda

The global response to COVID-19 demonstrated the dangers of vaccine inequity amidst acute shortages and monopoly of supply by high-income countries. By the end of 2021, almost one year after COVID-19 vaccines were made available, nearly 72% of people in both high-income and upper-middle income countries were fully vaccinated with two doses of COVID-19 vaccines, while only 35% and 4% of the people in lower-middle and low-income countries were fully vaccinated.

This pattern is not unique to the COVID-19 response; supply shortages and inequitable access to vaccines have affected responses to other disease outbreaks, like cholera, despite high demand for cholera vaccines and other medical countermeasures.

Barriers to vaccine access have dire consequences: one million people are still dying from vaccine-preventable diseases, and for the first time in three decades, global vaccination coverage among children is declining. These outcomes are concentrated in the world's poorest countries - the WHO Africa Region had nearly 20% of the world's disease burden in 2019.

A number of factors contribute to vaccine inequalities, including affordability, availability and accessibility. But the COVID-19 pandemic laid bare one systemic driver that - if addressed - could contribute to long-term progress on vaccine access in lower-income countries: tackling the disproportionate concentration of vaccine manufacturers in wealthier countries.

COVID-19 demonstrated Africa's particular vulnerabilities to vaccine access: it imports 99% of vaccines administered on the continent, and only 8 African countries have varying degrees of capacities to produce vaccines. More medicine manufacturing on the continent could help scale the availability of vaccines needed most on the continent in the long-term and smooth supply of countermeasures during future public health emergencies.

For African stakeholders, this is a matter of reducing dependency. In response to the inequities experienced throughout the COVID-19 pandemic, in 2021, the African Union and Africa CDC proposed an ambitious target to manufacture 60% of Africa's routine and outbreak immunization needs on the continent by 2040. To implement this target, the Partnerships for African Vaccine Manufacturing (PAVM) was formed. Its strategy outlines a roadmap to equity and health security and forms part of Africa CDC's New Public Health Order, operationalized in early 2023. This strategy looks to advance eight workstreams or programs (Figure 1) to drive demand and create supply for African vaccines, and eventually other countermeasures, over the long term.

Figure 1: PAVM Strategy Workstreams & Institutions Advancing Each

PAVM Strategy and Workstream	List of institutions advancing this workstream (non-exhaustive)
Market Designs & Demand Intelligence	African Vaccine Acquisition Trust/Task Team (AVAT/AVATT), African Continental Free Trade Area (AfCFTA), Gavi, Africa CDC
Access to finance	African Development Bank (AfDB), European Investment Bank (EIB), other Multilateral Developments Banks, PEPFAR
Regulatory Strengthening	African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), African Medicines Agency, AfCFTA, Africa CDC
Technology transfer and Intellectual Property	WHO Technology Transfer Hub, Coalition for Epidemic Preparedness Innovations (CEPI)
Research & Development	African Research University Alliance (ARUA), PANTHER
Talent Development	ARUA, African Vaccine Manufacturing Initiative (AVMI)
Infrastructure Development	AfDB, AfCFTA
Agenda Setting	PAVM Taskforce

Developments and considerations in Africa's regional manufacturing agenda

This regional agenda is nascent. Delivering on it in a sustainable way will require a long-term, strategic approach. The analysis below outlines three areas where efforts on regional manufacturing are advancing and offers considerations for next steps.

Market design and demand intelligence

The PAVM program aims to ensure market access for African vaccine manufacturers by exploring options like pooled procurement, targeted financial instruments, and prioritization of antigens:

- **Pooled procurement mechanisms.** Pooled procurement involves aggregating demand to ensure predictable volumes so that investments in manufacturing are de-risked. The PAVM program proposes expanding the African COVID-19 Vaccine Acquisition Trust and Task Team (AVAT/AVATT) to provide a pooled procurement mechanism for routine vaccines in countries not supported by Gavi. AVATT may initially start with those countries and a limited portfolio of products, with the opportunity to expand its portfolio and participating countries as more countries graduate from Gavi eligibility over the medium- to long-term.
- **Advanced Market Commitment (AMC).** Gavi's ten-point plan on manufacturing acknowledges the need for market shaping initiatives, such as an African Vaccine Market Accelerator, to complement options

like pooled procurement. Gavi is working with stakeholders to design a structured AMC to incentivize manufacturer entry without compromising market stability. Current concepts for the AMC include considering all finished products of Gavi-supported antigens and providing specific incentives for platform technologies to achieve improved pandemic preparedness and response (PPR). This will support local fill & finish and drug substance manufacturing and award incentives to African manufacturers providing doses to Gavi-eligible countries.

- **Priority list of pathogens.** Having a selected list of priority antigens that matches market needs is important for commercial viability. Encouragingly, the PAVM strategy, Africa CDC, and Gavi all have come up with their list of priority antigens. Because each of these have their own criteria for selection, these different lists are not fully aligned.

Access to Financing

Access to finance will be essential to successfully implement the PAVM strategy in Africa. African manufacturers, however, face challenges in securing affordable finance for building manufacturing capacity. To address this several initiatives are underway:

- **Low-interest Multilateral Development Bank (MDB) lending with longer payback periods.** MDBs offer low-interest lending with longer payback periods than private lenders, making them suitable for African manufacturers. The African Development Bank (AfDB), in line with its vision for Africa's pharmaceutical industry, has committed to invest $3 billion over 10 years.
- **Collaboration between development finance partners.** The new Africa health financing initiative, co-designed by health, financial, and technical experts from the European Investment Bank (EIB) and Afreximbank, will each provide new investments of €100 million for scaled production of safe, affordable, and effective medicines across sub-Saharan Africa. But it's not just the banks getting involved. The President's Emergency Plan for AIDS Relief (PEPFAR), a US initiative, is also collaborating with the United States Development Finance Corporation to finance eligible private sector projects that build regional manufacturing capacity for therapeutics, diagnostics, and ancillary supplies in lower-income countries, with a focus on Africa. These initiatives will contribute to the longer-term goal of holistic medicine manufacturing in Africa.

Talent development and transfer of technology and intellectual property

Investment in human resources is a key enabler of a sustainable vaccine manufacturing industry. Market shaping strategies and affordable financing need to complement building human skills and capacities, and sharing crucial knowledge around vaccine technologies and intellectual property.

- **Invest in human capital, not just infrastructure**: A key area where smaller but significant investments are needed is talent development, which also benefits job creation. Global and regional financing could fill the $20 million financing gap of the WHO Tech Transfer Hub, which supports technology transfer and human development in 15 countries that are part of its initiative.
- **Collaboration on knowledge, intellectual property and skills sharing**. The WHO Technology Transfer Hub aims to tackle the technology and knowledge gaps that currently slow down efforts to build more regionally diverse manufacturing capacities. In addition to technology transfer, the Hub is collaborating with local manufacturers, regulatory authorities, and other stakeholders to provide training and

technical assistance to build and strengthen local manufacturing capabilities. PAVM is also proposing a series of Capability and Capacity Centers to foster partnerships between research institutions, manufacturing companies, educational institutions, and CEPI's network of manufacturing partners. Concerns remain that intellectual property rights could hinder or slow down local production. The zero-draft of the Pandemic Accord acknowledges these concerns, and contains provisions that encourage greater transparency on pricing, technology transfer and data sharing in instances where research and development has attracted public funding.

- **Private partnerships.** The PAVM strategy highlights the need for various stakeholders, including private actors, to support its vision. It also highlights concerns around the lack of sufficient human capital and skills to resource the vaccine manufacturing value chain. InnoGlobal is one such private actor that aims to support PAVM's talent development program by focusing on building a range of skills across Africa. Its collaboration with public and private education and research institutions as well as investments in pilot facilities could help fill some of the gaps identified in the PAVM program, provided it aligns with PAVM's call for local talent development.

Conclusion & Next Steps

The COVID-19 pandemic increased demand for regional diversification of manufacturing capacity to address inequitable access to medical countermeasures like vaccines and treatments, and also to better prepare and respond to pandemics. Delivering this in a sustainable way will require a long-term and strategic approach.

First, in the immediate term, continued support for programs like Gavi, AVATT, and other regional or country-led immunization efforts are essential to ensure countries can scale routine immunization services now.

Over the medium term, several ongoing processes could be leveraged to advance progress towards meeting the target to manufacture 60% of Africa's routine and outbreak immunization needs on the continent by 2040. The Pandemic Accord, which is currently being negotiated, could provide the legal framework that supports the PAVM strategy to achieve its vision. African stakeholders could use the Pandemic Accord negotiations to strengthen provisions that facilitate transparency and accountability around research and development, technology transfer, and pricing.

A range of public and private actors are already collaborating on the various PAVM programs. Adopting a thematic approach under each program, such as a pooled procurement under the access to finance program, could help ensure that different initiatives complement one another to benefit the overall strategy.

Finally, to improve forecasting on demand, AVATT and Gavi (the largest single purchaser of vaccines in Africa) could be more transparent on purchasing agreements for pooled procurement; they should also systematically collaborate, to help ensure that all African countries - regardless of eligibility for - Gavi-support are able to acquire vaccines in a timely, efficient, and affordable manner. There is opportunity for the African Continental Free Trade Agreement to complement such a pooled procurement mechanism by ensuring trade-friendly policies for the low-cost movement of vaccines and medical products across borders. In addition, a list of priority antigens that match market needs with commercial viability requirements, aligned across organizations, such as Gavi, Africa CDC, and PAVM, would help send a clear demand signal for specific vaccines and medical countermeasures while also influencing the design of procurement and market-shaping mechanisms for these products.